

Protecting and Improving the Health of Iowans

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COVID-19 Vaccine Information Brief

April 22, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Vaccine Information Brief will be May 6, 2022

IMPORTANT/NEW COVID-19 Vaccine Information

- Interim Clinical Considerations for Use of COVID-19 Vaccines
- Shelf Lift Extension for Select Pfizer Products
- Moderna 14 Expired Doses
- COVID-19 Vaccine Administration Dashboard
- HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund
- Moderna Ancillary Kit Update
- Preventing Fraud or Theft of COVID-19 Vaccines and Vaccination Cards
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- Vaccine Expiration Date Resources
- V-Safe After Vaccination Health Checker

Interim Clinical Considerations for Use of COVID-19 Vaccines

CDC has updated its guidance for COVID-19 vaccination, including booster dose recommendations for:

- Added considerations for the option to receive a second COVID-19 vaccine booster dose
- Updated guidance for COVID-19 booster vaccination after SARS-CoV-2 infection

To view all updates, please visit <u>CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently</u>
Approved or Authorized in the United States.

Shelf Lift Extension for Select Pfizer Products

The Food & Drug Administration has approved an amendment to the EUA for Pfizer Tris COVID-19 vaccine extending the shelf-life of the following Pfizer product formulations from 9 to 12 months:

- Pfizer Tris Pediatric vaccine (Orange Cap for ages 5 through 11, with diluent)
- Pfizer Adult Tris (Gray Cap for ages 12+, no diluent)

Vials stored consistently in an ultra-low temperature freezer at -90oC to -60oC (-130oF to -76oF) may remain in use for up to 12 months beyond the date of manufacture printed on the vials and cartons. Vials stored in refrigerated vials (2oC to 8oC) are NOT eligible for extension, regardless of the expiration date. Additional information on Pfizer storage and handling may be found at Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC.

Pfizer Orange and Gray Cap Tris Vaccine expiry dates based on 12 months from the date of the manufacture are shown below and at Expiry Information for Pfizer COVID-19 Vaccines. No changes have been made to the vaccine itself to enable extension of expiry dating. This change is based on stability data submitted by the manufacturer to the FDA.

| Printed Manufacturing Date | 12-Month Expiry Date |
|----------------------------|-------------------------|
| 06/2021 | 31-May-2022 |
| 07/2021 | 30-Jun-2022 |
| 08/2021 | 31-Jul-2022 |
| 09/2021 | 31-Aug-2022 |
| 10/2021 | 30-Sep-2022 |
| 11/2021 | 31-Oct-2022 |
| 12/2021 | 30-Nov-2022 |
| 01/2022 | 31-Dec-2022 |
| 02/2022 | 31-Jan-2023 |
| 03/2022 | 28-Feb-2023 |

Reminders:

- Do not use Pfizer Tris products beyond 12 months from manufacture date.
- Expiration dates for the Pfizer TRIS products are NOT printed on the vaccine cartons or vials.
- Do not store Pfizer vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen.

For more information, please review the updated FDA Factsheets:

- Fact Sheet for Healthcare Providers Administering Vaccine (Gray Cap/Adult)
- Fact Sheet for Healthcare Providers Administering Vaccine (Orange Cap/PEDS)

COVID-19 vaccines authorized under an EUA do not have fixed expiration dates, and expiration dates may be extended as more stability data is collected. Always check Expiry Information for Pfizer COVID-19 Vaccines to obtain the most up-to-date expiration dates for the Pfizer COVID-19 vaccines you have in inventory.

COVID-19 Vaccine Administration Dashboard

Reporting of vaccination data to the <u>COVID-19 Vaccine Administration Dashboard</u> and DOMO will transition to monthly as of May 3, 2022. Additional data outside of these monthly timeframes will not be available.

Moderna 14 Expired Doses

As of April 8, 2022 all lots of Moderna 14 dose vials have expired and Moderna 14 is no longer available for ordering. Healthcare providers with Moderna 14 still in inventory need to immediately remove expired doses to prevent it from being administered.

Please review the below steps to ensure accurate vaccine inventory.

- Report vaccine wastage in IRIS.
 - Verify all vaccine wastage is documented appropriately using the approved adjustment reasons included in the *Adjusting COVID-19 Vaccine Inventory for Wastage* instructions.
 - VACCINE WASTAGE ADJUSTMENT REASONS CANNOT BE USED TO CORRECT VACCINE INVENTORY FOR UNACCOUNTED DOSES.

If you have questions regarding IRIS and vaccine inventory, contact the IRIS Help Desk at 1-800-374-3958.

Statement Regarding Exhaustion of Funding for Uninsured Program and Coverage Assistance Fund

The HRSA COVID-19 Uninsured Program has stopped accepting claims due to a lack of sufficient funds. Confirmation of receipt of claim submission does not mean the claim will be paid. Claims submitted by these deadlines will be paid subject to eligibility and availability of funds.

Unfortunately, IDPH does not have any information about efforts to continue to sustain this program. Provider questions can be directed to the HRSA COVID-19 Uninsured Program Provider Support Line: 866-569-3522, whose hours of operation are 8:00 am to 10:00 pm Central Time, Monday through Friday. For additional information, see COVID-19 Uninsured Program Claims Submission Deadline FAQs.

IDPH has received questions regarding the provider's ability to refuse COVID-19 vaccine to uninsured patients. CDC strongly encourages providers to stay in the CDC COVID-19 Vaccination Program and CDC expects participating providers will continue to administer these life saving vaccines at no cost to patients to ensure equitable access for all individuals. The COVID-19 Vaccination Program Provider Requirements website does offer guidance:

All organizations and providers participating in the CDC COVID-19 Vaccination Program:

- must administer COVID-19 Vaccine at no out-of-pocket cost to the recipient
- may not deny anyone vaccination based on the vaccine recipient's coverage status or network status
- may not charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided
- may not require additional medical services to receive COVID-19 vaccination
- may seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient, such as:
 - vaccine recipient's private insurance company
 - Medicare or Medicaid reimbursement
 - o HRSA COVID-19 Uninsured Program for non-insured vaccine recipients
- may not seek any reimbursement, including through balance billing, from the vaccine recipient

Moderna Ancillary Kit - Update

Moderna COVID-19 vaccine shipments will now come with *one ancillary kit* (1 ancillary kit to 1 carton of vaccine, instead of 2 ancillary kits to 1 carton of vaccine). This change will take effect with orders placed beginning on Monday, April 11, 2022, at 10:00 am ET.

Preventing Fraud or Theft of COVID-19 Vaccines and Vaccination Cards

To prevent COVID-19 Vaccination Cards from being stolen, fraudulently reproduced, and illegally sold to reflect full vaccination status for someone who has not received a COVID-19 vaccine, please consider the following strategies:

- Always secure COVID-19 vaccine vials and vaccination cards to protect them from inappropriate distribution.
- Monitor both the inventory of COVID-19 vaccine and blank vaccination cards and keep them locked up when not being used.

IDPH encourage reporting suspected fraud and theft incidences to local law enforcement agencies and to the HHS Office of Inspector General and/or the FBI as listed below:

- HHS Office of Inspector General (1-800-HHS-TIPS or www.oig.hhs.gov)
- Federal Bureau of Investigation Electronic Tip Form (http://tips.fbi.gov)

Surplus Vaccination Cards

Please shred or destroy unused surplus cards. If unable to do so, providers must keep extra vaccination cards in a secure location (under lock and key).

Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

At this time, the Medical Affairs team is continuing to educate providers on Purple, Gray, and Orange caps as well as medical updates. To access dates and links for upcoming training sessions, please visit: https://www.pfizermedicalinformation.com/en-us/medical-updates.

Vaccine Expiration Date Resources

Always be sure to check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines. It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expirations dates can be directed to the IRIS Helpdesk at 800-374-3958.

For EUA COVID-19 vaccines that do not have a final expiration date, the CDC has set an expiration date of 12/31/2069 to serve as a <u>placeholder date</u>. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website. It is important for healthcare providers to update vaccine expiration dates in IRIS.

The Pfizer COVID-19 vaccine:

It is important for all healthcare providers to double check all shelf life extensions for all Pfizer products.

Pfizer does not have an expiration date look up tool for these vaccines. The date on the label is <u>NOT</u> the expiration date, instead, each vial has the lot number and date of manufacture printed on the label. Pfizer does provide guidance for expiration dates on their <u>website</u>.

- Regardless of storage condition, <u>GRAY CAP</u> and <u>ORANGE CAP</u> vaccine vials should not be used after
 9 months from the **date of manufacture** printed on the vial and cartons.
- The <u>PURPLE CAP</u> vaccine vials with an **expiry date** of September 2021 February 2022 (printed on the label) may remain in use for 3 months beyond the printed date if vials are maintained in approved storage conditions (-90°C to -60°C, -130°F to -76°F).
- Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 (ORANGE CAP) years of age may be stored at refrigerated temperatures between 2°C and 8°C (36°F and 46°F) for up to 10 weeks. Vaccine initially distributed is nearing or has met the 10-week beyond-use date (BUD).
 - Reminders for providers:
 - Vaccine may be stored in a refrigerator unit between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
 - Do NOT use vaccines stored in the refrigerator after 10 weeks. Discard appropriately.
 - Use a tracking system to ensure the vaccine is not used after the BUD. CDC has tracking labels to monitor storage times at <u>Pfizer-BioNTech COVID-19 Vaccine</u> (5 <u>Through 11 Years of Age</u>) | <u>CDC</u>



| Printed Manufacturing Date | 9-Month Expiry Date |
|----------------------------|---------------------|
| 06/2021 | 28-Feb-2022 |
| 07/2021 | 31-Mar-2022 |
| 08/2021 | 30-Apr-2022 |
| 09/2021 | 31-May-2022 |
| 10/2021 | 30-Jun-2022 |
| 11/2021 | 31-Jul-2022 |
| 12/2021 | 31-Aug-2022 |
| 01/2022 | 30-Sep-2022 |
| 02/2022 | 31-0ct-2022 |
| 03/2022 | 30-Nov-2022 |

| Expiry information for Ages 12 years and older DILUTE BEFORE USE Purple Cap presentation | |
|--|---------------------|
| Printed Expiry Date | Updated Expiry Date |

| Printed Expiry Date | Updated Expiry Date |
|---------------------|---------------------|
| September 2021 | December 2021 |
| October 2021 | January 2022 |
| November 2021 | February 2022 |
| December 2021 | March 2022 |
| January 2022 | April 2022 |
| February 2022 | May 2022 |
| March 2022 | June 2022 |

Janssen COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.jnj/

Moderna COVID-19 vaccine:

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Go to www.modernatx.com/covid19vaccine-eua/

CDC's <u>COVID-19 Vaccine Expiration Date Tracking Tool</u> can help providers keep track of the expiration date by lot number.

V-safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: posted on the vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- V-safe after vaccination health checker website
- V-safe Print Resources
- V-safe Poster-11x17
- Vaccine Adverse Event Reporting System (VAERS)